CHAPTER 7
SECTION 10.1

REQUIREMENTS FOR FOOD AND DRUG ADMINISTRATION APPROVAL FOR MEDICAL DEVICES

ISSUE DATE: December 18, 1992
AUTHORITY: 32 CFR 199.2(b) and 32 CFR 199.4(g)(15)

I. DESCRIPTION

A. The statutory definition of a "medical device" is all-encompassing. Essentially, any item promoted for a medical purpose that does not rely on chemical action to achieve its intended effect is considered to be a medical device. In vitro diagnostic tests are also regulated as medical devices. This broad definition gives the FDA jurisdiction over a wide variety of products from chewing gum that contains an abrasive food additive for its antiplaque properties to software that analyzes the output of a cardiac monitor.

B. The Food and Drug Administration (FDA) places all medical devices into one of three classes. The class dictates the degree of regulatory control needed to assure safety and effectiveness of the device. They are as follows:

1. Class I - Devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness. Examples of Class I devices are enema kits, elastic bandages, and pipetting.

2. Class II - Devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness. Examples of Class II devices include power wheelchairs and pregnancy test kits.

3. Class III - Devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval. Examples of Class III devices include implantable pacemaker pulse generators, automated heparin analyzers, and infant radiant warmers.

C. There are two main routes to the market for a new device. If the manufacturer can establish substantial equivalence, premarketing notification (510(k)) approval is all that is required. Otherwise, full premarketing testing and approval are required. The premarketing approval process is lengthy since it requires review and analysis of all completed studies, trials and literature.

1. Premarket notification is also known as a "510(k) submission," since the basic requirement for it is in Section 510(k) of the Federal Food, Drug, and Cosmetic Act. Premarket notification must be submitted at least 90 days before the manufacturer anticipates marketing the device. The reason for notifying FDA that a device is about to be marketed is to let FDA determine whether or not the device is substantially equivalent to one already in commercial distribution. If the FDA determines that the device is substantially equivalent, the manufacture is free to market it.

2. According to the FDA, the term "substantially equivalent" is not intended to be so narrow as to refer to devices which are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The term is to be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to the safety and effectiveness.

D. General controls apply to all three classes of devices and include registration, premarketing notification, record keeping, labeling, reporting of adverse experiences and good manufacturing practices.

E. FDA approved devices are published in the U.S. Department of Health and Human Services Classification Names for Medical Devices and Classification Names for In Vitro Diagnostic Products.

F. The FDA grants a Humanitarian device Exemption (HDE) to manufacturers of rare disease devices that are intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. Manufacturers ordinarily must provide FDA evidence from studies showing that products are both safe and effective. However, an approved HDE authorizes marketing of the humanitarian use devices (HUD) as long as manufacturers show that the device is safe and has a probable benefit to patients, rather than on clinical studies to establish effectiveness.

G. The FDA grants an Investigational Device Exemption (IDE) to a researcher using a device in studies undertaken to develop safety, effectiveness and other data for that device when such studies involve the use of human subjects. An approved IDE permits a device that would otherwise be subject to marketing clearance to be shipped lawfully for the purpose of conducting a clinical study. The FDA categorizes devices being studied in clinical trials under IDEs. The FDA assigns each device with an FDA-approved IDE to one of two categories:

1. Experimental/Investigational (Category A) devices are innovative devices in Class III for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective).

2. Non-Experimental/Investigational (Category B) devices are devices believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

II. POLICY

Class I, Class II, and Class III devices with premarket approval, i.e., (510)(k), approved by the Food and Drug Administration are covered when the following conditions are met:

1. The device is approved by the FDA for commercial marketing for a specific FDA approved application and is medically necessary for the treatment of the condition for which the device is intended to be used.

2. The device is approved by the FDA is medically necessary, and reliable evidence supports the application is safe, effective, and in accordance with nationally accepted standards of practice in the medical community. If the nonapproved FDA application of the device is not in accordance with nationally accepted standards of practice in the medical community and/or safety and/or effectiveness is questionable, then cost-sharing of the device is not allowed.

3. A humanitarian use device approved for marketing through a Humanitarian Device Exemption application may be cost-shared. Coverage of any such device is subject to all other requirements of the law and rules governing TRICARE.

4. TRICARE will consider for coverage a device with an FDA-approved IDE categorized by the FDA as non-experimental/investigational (FDA Category B) for beneficiaries participating in FDA-approved clinical trials. Coverage of any such Category B device is dependent on its meeting all other requirements of the law and rules governing TRICARE and upon the beneficiary involved meeting FDA-approved IDE study protocols.

5. Devices with a FDA-approved IDE categorized by the FDA as non-experimental/investigational (FDA Category B), which was the subject of an FDA approved clinical trial(s), may be considered for coverage once it receives FDA approval for commercial marketing. Coverage is dependent on the device meeting the FDA requirements/conditions of approval and all other requirements governing TRICARE.

III. EXCLUSION

Experimental/Investigational (Category A) IDEs.

IV. EFFECTIVE DATES

A. Device used for an FDA-approved application - Effective date is the date of the FDA approval.

B. Device used for a non-FDA approved application - Effective date is the date the reliable evidence supports the application is safe, effective, and in accordance with nationally accepted standards of practice in the medical community.

C. Category B IDEs - Effective date is the date the device is classified as a Category B device by the FDA.

- END -